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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,668	10/17/2005	Herwig Buchholz	MERCK-2686-1	1550
23599 7590 02/04/2009 MILLEN, WHITE, ZELANO & BRANIGAN, P.C. 2200 CLARENDON BLVD. SUITE 1400 ARLINGTON, VA 22201				
EXAMINER				
BLAKELY III, NELSON CLARENCE				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/553,668

Applicant(s)

BUCHHOLZ ET AL.

Examiner

NELSON C. BLAKELY III

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 6, 7, 9, 14-18, 20-25 and 28-32 is/are pending in the application.
- 4a) Of the above claim(s) 17, 18, 20-25 and 28-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 6, 7, 9 and 14-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Application Status

Claims 1, 2, 6, 7, 9, 14-18, 20-25 and 28-32 of the instant application are pending. Claims 17, 18, 20-25 and 28-32 are withdrawn, and claims 3-5, 8, 10-13, 19, 26, 27, 33 and 34 are canceled pursuant to Applicant's Amendment, filed 10/14/2008. Accordingly, instant claims 1, 2, 6, 7, 9 and 14-16 are presented for examination on their merits.

Election/Restrictions

Applicant's election with traverse of Group I, drawn to an antimicrobial pigment, comprising one or more inorganic pigments and silver oxide, in the reply filed on 03/07/2008, and Applicant's arguments, filed 10/14/2008, are acknowledged. The traversal is on the ground(s) that unity of invention for the combination of an independent claim to a product, a process specially adapted for manufacturing the product, and the use of the product does not required a technical feature that defines a contribution over the prior art. Applicant's traversal has been carefully considered in its entirety, but is not found persuasive. The requirement of unity of invention, referred to in Rule 13.1, shall be fulfilled only wherein there is a technical relationship among those inventions involving one or more of the same or corresponding technical features. The expression "special technical features" shall mean those technical features that define a

contribution when each of the claimed inventions, considered as a whole, makes over the prior art.

Accordingly, by the reasons mentioned *supra*, and those made of record at pages 3 and 4 and pages 2 and 3 of the previous Office Actions, mailed 02/13/2008 and 05/14/2008, respectively, the requirement is still deemed proper, and the finality is maintained.

Applicant's Amendment

Applicant's Amendment, filed 10/14/2008, wherein the specification and claims 1, 2 and 6 are amended, and claims 3-5, 8, 10-13, 19, 26, 27, 33 and 34 are canceled, are acknowledged and have been fully considered.

Terminal Disclaimer

Applicant's Terminal Disclaimer, filed 10/14/2008, is acknowledged. However, confusingly, Applicant recites that the instant application disclaims the terminal part of the statutory term of any patent granted on the instant application, which would extend beyond the expiration date of the full statutory term of prior U.S. Patent No. 6,372,236. Accordingly, the nonstatutory obviousness-type double patenting rejection of record is not based on the claims of U.S. Patent No. 6,372, 236, but of the co-pending U.S. application no. 10/553,671, in view of Park *et al.* (U.S. Patent No. 6,372,236). Additionally, U.S. Patent No. '236 is not commonly owned. Therefore, the Terminal Disclaimer, filed 10/14/2008, appears to be improper, and not sufficient to overcome the

instant nonstatutory obviousness-type double patenting rejection. Clarification is required.

Objections

Specification (Withdrawn)

The previous objection to the specification is hereby **withdrawn** pursuant to Applicant's Amendment, filed 10/14/2008.

Specification (New)

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Appropriate correction is required.

Claim Objections (Withdrawn)

The previous objections to the claims are hereby **withdrawn** pursuant to Applicant's Amendment, filed 10/14/2008.

Claim Objections (New)

Claim 1 is objected to for the following informalities:

With regard to instant claim 1, Applicant is encouraged to use the recitation "obtained" in lieu of "obtainable". Additionally, Applicant is encouraged to use a lowercase "e" in the recitation "CE₂O₃".

Appropriate correction is required.

Claim Rejections - 35 USC § 112 (Withdrawn and Maintained)

The previous rejection, with regard to instant claims 1-13, 15 and 16, is hereby **withdrawn** pursuant to Applicant's Amendment, filed 10/14/2008.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 14 remains rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is noted that Applicant failed to respond to the previously set forth rejection of claim 14.

Independent claim 1 discloses an antimicrobial pigment comprising one or more inorganic pigments and silver oxide; however, claim 14 recites "inorganic pigments and antimicrobial pigments" as two distinct entities, so it is confusing as to whether the antimicrobial pigments, in fact, comprise the inorganic pigments of claim 14, or if there

are additional inorganic pigments of the claimed invention. Appropriate clarification is required by Applicant.

Response to Arguments

Applicant's arguments with respect to claim 16, previously rejected under 35 U.S.C. 112, second paragraph, have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112 (New)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 16 recites the limitation "antimicrobial compound" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103 (Withdrawn)

The previous rejection to the claims is hereby withdrawn pursuant to Applicant's Amendment, filed 10/14/2008.

Response to Arguments

Applicant's arguments with respect to claims 1, 2, 6, 7, 9 and 14-16, previously rejected under 35 U.S.C. 103(a), have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103 (New)

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, 6, 7, 9 and 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seo *et al.* (U.S. Patent No. 6,030,627; Cited by Applicant), in view of Abe *et al.* (U.S. Patent No. 4,375,373) and Bagala, Sr. (U.S. Patent No., as evidenced by Iler (U. S. Patent No. 2,885,366) and Galinsky *et al.* ["Basic Pharmacokinetics and Pharmacodynamics." in: Remington: The Science and Practice of Pharmacy (Baltimore, Lippincott Williams & Wilkins, 2006), p. 1171].

With regard to instant claims 1, 2, 6, 7, 9 and 14-16, Seo *et al.* disclose, in reference claims 1, 3, 4 and 7, an antimicrobial cosmetic pigment comprising inorganic cosmetic pigment, amorphous glassy coating layer of metal oxide having a lattice structure formed over the surface of said inorganic cosmetic pigment and antimicrobial metals or antimicrobial metal ions intercalated inside the lattice structure of said coating layer of metal oxides. In the instant excerpt, Seo *et al.* further disclose wherein the inorganic cosmetic pigment may be mica, zinc oxide and titanium oxide, for example, and wherein the coating layer of metal oxide comprises one or more of zinc oxide and ferric oxide (dopant), for example. Furthermore, in the instant excerpt, Seo *et al.* disclose wherein the antimicrobial metal is one or more of silver and zinc, for example. Seo *et al.* disclose, in column 5, lines 33-45, wherein the composition of the coating layer of the metal oxides is generally similar to glass, and as a means of preventing the decrease of its function as a cosmetic pigment because of the transparency due to its lower refractive index, a small quantity of ferric oxide, for example, is added, for coloring purposes, as an inorganic coloring agent.

Seo *et al.* fail to disclose specifically wherein said pigment comprising one or more inorganic pigments and silver oxide is obtained by agitating a suspension at 20-45 °C, or wherein the amount of the antimicrobial compound is in the range of 0.001 to 10% by weight, based on the inorganic pigment. However, Abe *et al.* disclose, in column 1, lines 19-21, wherein the pigments of the reference invention may be used in cosmetics, for example. In column 4, lines 15-42, Abe *et al.* disclose where any type of metal powder pigment, i.e., silver and zinc, may be used in the reference invention. In

the instant excerpt, Abe *et al.* further disclose wherein the inorganic pigment may comprise titanium dioxide and zinc oxide, for example. Abe *et al.* disclose, in column 5, line 25, through column 6, line 5, a process wherein the inorganic pigments may be covered with a hydrous metal oxide, such as titanium. In the instant excerpt, Abe *et al.* further disclose wherein an aqueous slurry of one or more fine hydrous oxides, such as titanium, is mixed so that the pigment particles are covered with the deposit of hydrous oxides. Furthermore, in the instant excerpt, Abe *et al.* disclose wherein an aqueous solution of the metal malts, such as titanium salt, is gradually added to the aforementioned slurry while it is stirred at room temperature (20-30 °C), or with heating. Additionally, in column 11, lines 7-24, Abe *et al.* disclose where the metal powder pigment is preferably coated in an amount of about 3 to 15 weight percent with respect to the pigment particles. Though Seo *et al.* disclose, in column 5, lines 33-45, wherein the composition of the coating layer of the metal oxides comprises a small quantity of ferric oxide, for example, for coloring purposes, as an inorganic coloring agent, Seo *et al.* and Abe *et al.* fail to disclose specifically wherein the L, a and b values are $-6 \leq \Delta L \leq 6$, $-5 \leq \Delta a \leq 5$ and $-5 \leq \Delta b \leq 5$, respectively. However, it is not inventive to discover the optimum ranges or regimens by routine experimentation when general conditions of a claim are disclosed in the prior art. See *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) and MPEP §2144.05(II). In addition, Galinsky *et al.* recite in the left column of page 1171, lines 12-27 of text, that it is recognized that drug therapy may be optimized by designing regimens that account for the concentration of a drug, for example, to achieve a desired pharmacological response. Therefore, the determination

of the optimum characterization of the pigment and optimum ranges would have been a matter well within the purview of one of ordinary skill in the art, at the time of the invention, through no more than routine experimentation. A skilled artisan would have envisaged the antimicrobial cosmetic pigment comprising inorganic pigment, amorphous glassy coating layer of metal oxide, i.e., titanium dioxide, and antimicrobial metals, i.e., silver, as disclosed by Seo *et al.*, prepared by stirring, or agitating, a slurry, or suspension, at room temperature (20-30 °C), or with heating, as disclosed by Abe *et al.* One of ordinary skill in the art, at the time of the invention, would have been motivated to combine the teachings of the aforementioned references when seeking a heat, chemical, and light resistant, stable antimicrobial inorganic pigment. It would have been obvious to one of ordinary skill in the art, at the time of the invention, because the combined teachings of the prior art are fairly suggestive of the claimed invention.

Seo *et al.* fail to disclose specifically wherein the mica is a synthetic mica, or wherein one or more layers of transparent, semitransparent or opaque, selectively absorbing, nonselectively absorbing or nonabsorbing metal oxides, i.e. titanium oxide, are arranged as alternating layers wherein the refractive index $n > 1.8$ and $n \leq 1.8$. However, Bagala, Sr. discloses, in reference claims 1-8, an effect pigment comprising metal oxide-coated laminar platelets in which the platelets are a mixture of about 5 to 90% platy glass and 90 to 5% mica, and in which the effect pigment exhibits visual homogeneity. in the instant excerpt, Bagala, Sr. further discloses wherein the metal oxide comprises iron and/or titanium oxides, and wherein the metal oxide coating comprises a plurality of layers. Additionally, in column 1, lines 44-58, Bagala, Sr.

discloses that the addition of coatings to a platelet so that the luster, color, and color homogeneity are maintained is a very complex process, and originally, the only platy substrate which achieved any significant use in commerce was mica. Furthermore, in the instant excerpt, Bagala, Sr. discloses that historically, the largest class of effect pigments based on thin film interference were those based on a mica substrate, and it became evident that other substrates, such as synthetic mica, could be used since it contributes certain effect attributes, due to variations in transparency, refractive index, bulk color, thickness and surface and edge features, for example. Therefore, a skilled artisan would have envisaged modifying the antimicrobial cosmetic pigment comprising inorganic pigment, amorphous glassy coating layer of a metal oxide, i.e., titanium oxide, and antimicrobial metals, i.e., silver, as disclosed by Seo *et al.*, prepared by stirring, or agitating, a slurry, or suspension, at room temperature (20-30 °C), or with heating, as disclosed by Abe *et al.*, such that the inorganic pigment comprises metal oxide-coated laminar platelets, i.e., synthetic mica, as disclosed by Bagala, Sr. One of ordinary skill in the art, at the time of the invention, would have been motivated to combine the teachings of the aforementioned references when seeking a visually homogeneous blend of coated effect pigments with antimicrobial activity. It would have been obvious to one of ordinary skill in the art, at the time of the invention, because the combined teachings of the prior art are fairly suggestive of the claimed invention.

Seo *et al.* fail to disclose specifically wherein the inorganic pigments are platelet-shaped, spherical or needle-shaped; however, Iler discloses in column 1, lines 15-42, wherein the products of the reference invention ordinarily assume the form of finely

divided spheres, plates, or fibers, i.e., needle-shaped. Additionally, in column 3, lines 1-17, Iler discloses wherein the substrates, comprising metal oxides, i.e., titanium dioxide and zinc oxide are typical of cores, whereas plate-like mineral silicates include various varieties of mica, for example. Therefore, a skilled artisan would have envisaged the antimicrobial effect pigments of the combined teachings of Seo *et al.*, Abe *et al.* and Bagala, Sr. to conform to a spherical or platelet-like shape, as evidenced by Iler. It would have been obvious to one of ordinary skill in the art, at the time of the invention, because the combined teachings of the prior art are fairly suggestive of the claimed invention.

Accordingly, the instant invention, as claimed in claims 1, 2, 6, 7, 9 and 14-16, is *prima facie* obvious over the combination of the aforementioned teachings.

Response to Arguments

Applicant's arguments with respect to claims 1, 2, 6, 7, 9 and 14-16, previously rejected on the ground of nonstatutory obviousness-type double patenting, have been considered but are moot in view of the new ground(s) of rejection.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29

USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2, 6, 7, 9 and 14-16 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 6-15, 18, 34, 38, 39, 41 and 42 of copending Application No. 10/553,671 ('671).

Although the conflicting claims are not identical, they are not patentably distinct from each other because U.S. application no. '671 claims a formulation for topical applications comprising pigment particles obtainable by agitating a suspension comprising one or more inorganic pigments and silver oxide, wherein said pigment particles with silver oxide are prepared by agitating said suspension at a temperature between 10 °C and 60 °C. U.S. application no. '671 also claims wherein said inorganic pigment particles are effect pigments, i.e., synthetic mica, and are platelet-shaped, spherical, or needle-shaped. Furthermore U.S. application no. claims wherein the substrates are coated with one or more layers of transparent, semitransparent or opaque, selectively absorbing, nonselectively absorbing or nonabsorbing metal oxides, such as TiO₂, arranged as alternating layers with a refractive index $n > 1.8$ and $n \leq 1.8$, which may additionally contain organic and/or inorganic colorants or elements as

dopant. U.S. application no. '671 additionally claims wherein the L, a and b values are - $6 \leq \Delta L \leq 6$, $-5 \leq \Delta a \leq 5$ and $-5 \leq \Delta b \leq 5$, respectively. U.S. application no. '671 claims wherein the silver oxide is substituted by zinc oxide, and wherein the antimicrobial compound is in the range of 0.001 to 10% by weight, based on the inorganic pigment. Therefore, a provisional obviousness-type double patenting rejection with regard to claims 1, 2, 6, 7, 9 and 14-16 is proper.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NELSON C. BLAKELY III whose telephone number is (571) 270-3290. The examiner can normally be reached on Mon - Thurs, 7:00 am - 5:30 pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Phyllis G. Spivack/
Primary Examiner, Art Unit 1614
February 1, 2009

/N. C. B. III/
Examiner, Art Unit 1614